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**ATTORNEY DOCKET: 0492611-0507 (MIT 10396)**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Chen, et al.  
Serial No: 10/674,087  
Filed: September 29, 2003  
For: Compositions and Methods for Delivery of Short Interfering RNA and Short Hairpin RNA

Art Unit:  
Examiner: 1644

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**TRANSMITTAL LETTER**

Enclosed are the following documents:

1. Form PTO-1449 (3 pages);
2. Supplemental Information Disclosure Statement (5 pages);
3. Transmittal Letter (1 page)
4. Cited Art (50); and
5. Return Postcard.

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

Monica R. Gerber, M.D., Ph.D.  
Reg. No. 46,724

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(617) 248-5000  
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Dated: Sept. 9, 2005  
3980661v1

**Certificate of Mailing**

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

9/9/05  
Date

Justin Blanch  
Signature

Justin Blanch

Typed or Printed Name of person signing certificate



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P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to the duty of disclosure under 37 CFR §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

**Type of Statement**

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or  
☒ A *supplemental* Information Disclosure Statement.

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Date 9/9/05

Justin Blanch  
Signature

Justin Blanch  
Name of Person Signing

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☒ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual

designated in § 1.56(c) more than three months prior to the filing of  
the information disclosure statement; or

☐ Includes herewith the fee set forth in § 1.17(p),

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under  
§ 1.113, a notice of allowance under § 1.311, or an action that otherwise closes  
prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure  
statement was first cited in any communication from a foreign  
patent office in a counterpart foreign application not more than  
three months prior to the filing of the information disclosure  
statement; or

☐ That no item of information contained in the information  
disclosure statement was cited in a communication from a foreign  
patent office in a counterpart foreign application, and, to the  
knowledge of the person signing the certification after making  
reasonable inquiry, no item of information contained in the  
information disclosure statement was known to any individual  
designated in § 1.56(c) more than three months prior to the filing of  
the information disclosure statement; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each cited reference not indicated with an asterisk is included;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☒ Does not contain non-English language citations;
- ☐ Includes one or more translations of a non-English citation; or
- ☐ Does contain non-English language citations, of which the following is a concise explanation:

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC §102.

It is respectfully requested that:


1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Dated:

Sept 9, 2005

Respectfully submitted,

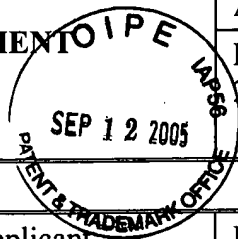


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<b>Form PTO-1449</b> <b>(REV. 8-83)</b> <b>SUPPLEMENTAL</b> <b>INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket: 0492611-0507	In re Application No. 10/674,087
	Applicant: Chen, et al.		
	Filing Date: September 29, 2003	Group: 1644	



### U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	5,580,767	Cowsert, et al.	Dec. 3, 1996.	435	172.3
	5,637,573	Agrawal, et al.	Jun. 10, 1997	514	44
	6,107,094	Crooke, et al.	Aug. 22, 2000	435	455
	6,117,657	Usman, et al.	Sep. 12, 2000	435	91.31
	6,495,675	Takaku, et al.	Dec. 17, 2002	536	24.5
	6,506,559	Fire, et al.	Jan. 14, 2003	435	6
	6,544,958	Wong, et al.	Apr. 8, 2003	514	44
	6,573,099	Graham, et al.	Jun. 3, 2003	435	455

### U.S. PATENT APPLICATIONS

Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:
	2002/0086356	Tuschl, et al.	Jul. 4, 2002	435	69.1
	2002/0132346	Cibelli, et al.	Sep. 19, 2002	435	455
	2002/0132788	Lewis, et al.	Sep. 19, 2002	514	44
	2002/0162126	Beach, et al.	Oct. 31, 2002	800	8
	2002/0173478	Gewirtz, et al.	Nov. 21, 2002	514	44
	2003/0027783	Zernicka-Goetz, et al.	Feb. 6, 2003	514	44
	2003/0049835	Helliwell, et al.	Mar. 13, 2003	435	320.1
	2003/0051263	Fire, et al.	Mar. 13, 2003	800	13
	2003/0055020	Fire, et al.	Mar. 20, 2003	514	44
	2003/0056235	Fire, et al.	Mar. 20, 2003	800	8
	2003/0068821	Lois-Caballe, et al.	Apr. 10, 2003	435	456
	2003/0074684	Graham, et al.	Apr. 17, 2003	800	278
	2003/0092180	Lewis, et al.	May 15, 2003	435	455
	2003/0104401	Lin, et al.	Jun. 5, 2003	435	6
	2003/0108923	Tuschl, et al.	Jun. 12, 2003	435	6
	2003/0124513	McSwiggen, et	Jul. 3, 2003	435	5

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	Applicant: Chen, et al.				
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		al.			
	2003/0125239	Crisanti, et al.	Jul. 3, 2003	514	7
	2003/0125281	Lewis, et al.	Jul. 3, 2003	514	44
	2003/0139363	Kay, et al.	Jul. 24, 2003	514	44
	2003/0143587	Dean, et al.	Jul. 31, 2003	435	6
	2003/0144232	Agami, et al.	Jul. 31, 2003	514	44
	2003/0148519	Engelke, et al.	Aug. 7, 2003	435	455
	2003/0150017	Mesa, et al.	Aug. 7, 2003	800	279
	2003/0175965	Lowe, et al.	Sep. 18, 2003	435	455
	2004/0167087	Aigner, et al.	Aug. 26, 2004	514	44
	2005/0074757	Kreutzer, et al.	Apr. 7, 2005	435	6
	2005/0100907	Kreutzer, et al.	May. 12, 2005	435	6

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	EP 1144623	Europe	28, 8, 2002		
	WO 00/63364	International	28, 10, 2000		
	WO 03/070918	International	28, 8, 2003		
	WO 03/074654	International	12, 9, 2003		

#### OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Abe, et al., "Antisense Therapy Of Influenza" European Journal Of Pharmaceutical Sciences" 13: 61-69, 2001.
	Bitko, et al., "Phenotypic Silencing Of Cytoplasmic Genes Using Sequence-Specific Double-Stranded Short Interfering RNA And Its Application In The Reverse Genetics Of Wild Type Negative-Strand RNA Viruses" BMC Microbiol 1: 34, 2001.
	de Semir, et al., "Non-Viral Vector-Mediated Uptake, Distribution , And Stability Of Chimeraplasts In Human Airway Epithelial Cells." The Journal Of Gene Medicine 4: 308-322, 2002.
	Gautam, et al., "Enhanced Gene Expression In Mouse Lung After PEI-DNA Aerosol Delivery" Molecular Therapy 2(1): 2000.
	Gitlin, et al., "Short Interfering RNA Confers Intracellular Antiviral Immunity In Human



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<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)		Filing Date: September 29, 2003	Group: 1644
	Cells" <i>Nature</i> <b>418</b> : 430-434, 2002.		
	Hatta, et al., "Inhibition Of Influenza Virus RNA Polymerase And Nucleoprotein Gene Expression By Unmodified, Phosphorothioated, And Liposomally Encapsulated Oligonucleotides" <b>223</b> : 341-346, 1996.		
	Hojoh, et al., "RNA Interference RNAi Induction With Various Types Of Synthetic Oligonucleotide Duplexes In Cultured Human Cells" <i>FEBS Letters</i> <b>521</b> : 195-199, 2002.		
	Massaro, et al., "Noninvasive Delivery Of Small Inhibitory RNA And Other Reagents To Pulmonary Alveoli In Mice" <i>Am J Physiol Lung Cell Mol Physiol</i> <b>287</b> : L1066-L1070, 2004.		
	Tsapis, et al., "Trojan Particles: Large Porous Carriers Of Nanoparticless For Drug Delivery" <i>Proc. Natl. Acad. Sci.</i> <b>99(19)</b> : 12001-12005, 2002.		
	Zhang, et al., "Inhibition Of Respiratory Syncytial Virus Infection With Intranasal siRNA Nanoparticles Targeting The Viral NS1 Gene" <i>Nature Medicine</i> <b>11(1)</b> : 2005.		
	Zhang, et al., "Small Interfering RNA Targeting Heme Oxygenase-1 Enhances Ischemia-Reperfusion-Induced Lung Apoptosis" <i>The Journal of Biological Chemistry</i> <b>279(11)</b> : 10677-10684, 2004.		
<b>EXAMINER</b>	<b>DATE CONSIDERED</b>		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			